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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,237	04/17/2004	Daniel R. Burnett	35744-01110	9644

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
02/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,237	BURNETT, DANIEL R.	
	Examiner	Art Unit	
	PHILIP WIEST	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,33 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,33 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/07 has been entered.

Response to Amendment

1. In the response filed 12/28/07, applicant amended claims 1, 5, 6, and 33, and added new claims 36 and 37.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 6,264,625).

3. With respect to Claims 1 and 36, Rubenstein et al. disclose an implantable fluid management system comprising a first tube member (2, 64) having a first end 68 and a second end (at 58) and a length which defines a lumen therethrough, a pump 72 fluidly coupled to the first member, and an integrated controller 10 for controlling and actuating the pump (Column 7, Lines 51-67). See Figures 9 and 10A. The system carries a fluid from a first body cavity to a second body cavity (Column 5, Lines 42-45 and Figure 10A). Because the system is designed for implantation inside the human body and is in constant contact with bodily fluids, it is inherent that the system, including the pump, will be made of a biocompatible material. Furthermore, a portion of the drainage system is

coated with antibodies specific to particular agents present in cerebrospinal fluid (Column 9, Lines 48-53). Rubenstein et al., however, does not specifically disclose that the pump is disposed in a housing having an anti-infective coating. Because the container 52 is coated with antibodies (i.e. an anti-infective coating), Rubenstein et al. clearly anticipates the need for bacteria and other infective agents in the CSF to be neutralized prior to fluid transfer. Therefore, it would have been obvious to one skilled in the art at the time of invention to also provide a coating of antibodies on the pump housing in order to prevent the transfer of infective agents when CSF is drained.

4. With respect to Claim 2, Rubenstein et al. discloses that the controller is a valve 140 located within the pump 72 (Column 10, Lines 50-51). See Figure 10D.

5. With respect to Claims 3 and 4, Rubenstein et al. discloses a pressure sensor 30 disposed on the end of each tube member (Column 9, Lines 27-36) that is programmed to send a signal to the control unit, thereby actuating the pump (18, 72) and flow-controlling valves 24 when a predetermined pressure is experienced (Column 7, Lines 51-67).

6. With respect to Claim 7, Rubenstein et al. further discloses a second tube member (2, 66) defining a lumen therethrough. Said second tubing member (2, 66) comprises a second pressure sensing element 30 at its tip 70 (Column 9, Lines 35-36). Said second pressure sensing element is configured to control the pump 72 (Column 7, Lines 51-67). See Figures 7 and 9.

7. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Wong et al. (US 5,947,911). Rubenstein discloses the fluid management system of Claim 1 and the placement of sensors at the end of each catheter, said sensors communicating with the pump to control the flow of fluid through the system (see rejection above). Rubenstein, however, does not disclose that the sensors are chemical sensors that detect the presence of a chemical composition. Wong et al. (hereafter Wong) discloses a device for monitoring blood chemistry comprising ab implanted blood chemistry sensor 19, an analyzer 25, a system controller 23, and a pump 13 (see Figure 1). The implanted sensor 19 is capable of detecting various chemical parameters including concentrations of oxygen, carbon dioxide, potassium, calcium, and sodium (Column 1, Lines 51-60). The analyzer 25 receives blood chemistry data from the sensor 19 and relays said data to the controller 23. The controller then operates the pump based on the received data. The method of controlling a medical fluid flow pump based on the presence of chemicals is therefore established in the art. It would have been obvious to one skilled in the art at the time of invention to combine the device with pump control based on sensor output of Rubenstein with the Wong's use of chemical sensors to operate an infusion pump because doing so would allow the concentration of various chemicals in the body cavities to be controlled.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Burbank (US 6,193,684). Rubenstein discloses the device of

Claim 1 substantially as claimed, but does not specifically disclose that the system comprises anchoring means opposing the forces generated by the pump. Burbank discloses an implantable physiological fluid shunt that is anchored to the abdominal wall of a patient using adhesives, staples, sutures, or any other known attachment method (Column 5, Lines 23-43). As is established in the art, the attachment of the device to the abdominal wall prevents migration of the device, thereby ensuring that fluid flow from the body cavity is not interrupted. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to one of ordinary skill in the art to modify the fluid management system of Rubenstein with the use of staples, adhesive, or other known attachment means of Burbank in order to securely attach the housing of the device to a location nearby the fluid transfer location, thereby preventing fluid communication from being interrupted by shunt migration.

9. Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Gorsuch (5,980,478). Rubenstein discloses the device of Claim 1, but does not specifically disclose that the system comprises coatings that promote fibrotic ingrowth and prevent bacterial adhesion to the device. Gorsuch discloses an implantable fluid transfer shunt that comprises an anti-infective coating that prevents bacteria adhesion to the housing, thereby reducing the risk of infection (Column 2, Line 55 through Column 3, Line 1). Gorsuch further discloses a fibrous cuff 26 that provides a substrate for tissue ingrowth. The ingrowth of tissue prevents foreign bacteria from entering the housing and helps to anchor the housing in place (Column 3,

Lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid management system of Rubenstein with the use of anti-infective coatings and fibrotic ingrowth-promoting materials of Gorsuch in order to reduce the risk of bacterial buildup inside the device and provide further anchoring means.

Response to Arguments

10. Applicant's arguments filed 12/28/07 with respect to claims 1-7 have been fully considered but they are not persuasive.

11. Applicant's arguments with respect to claims 33 and 35-37 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Claims 1-4 and 7, applicant argues that Rubenstein does not provide motivation to provide an anti-infective coating on the surface of the pump. This argument has not been found persuasive. Rubenstein clearly states that the inner portions of the device may be coated with antibodies, as explained above. It would have been obvious to apply the same coatings to the pump, which also comes into contact with the fluid.

With respect to Claims 5 and 6, Woo clearly suggests the method of monitoring the chemical compisition of fluid passing through the shunt. The analyzer being positioned outside the body has no bearing on the function of the device. The analyzer is also fully capable of being implanted in the body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761